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30237-49949 CHUE



Agenzia Italiana del Farmaco
AIFA

Part 2

Certificate No: IT/71-2/H/2017

Name and address of the site.

GLAXOSMITHKLINE MANUFACTURING S.P.A. - VIA
A. FLEMING, 2 - 37135 VERONA (VR)

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Human Medicinal Products

Part 1

Authorised Operations

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:

The manufacturer GLAXOSMITHKLINE MANUFACTURING S.P.A.

Site address VIA A. FLEMING, 2 - 37135 VERONA (VR)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 43/2017 dated 03/02/2017 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/16/2016, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

AIFA: Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel. +390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 2559

PC
GMP



Agenzia Italiana del Farmaco

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Part 2

Name and address of the
site:

GLAXOSMITHKLINE MANUFACTURING S.P.A. - VIA
A. FLEMING, 2, 37135 VERONA (VR)

GLAXOSMITHKLINE MANUFACTURINGS.P.A. - VIA
A. FLEMING, 2, 37135 VERONA (VR)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

| | |
|-----|---|
| 1.1 | Sterile Products |
| | 1.1.1 Aseptically prepared |
| | 1.1.1.6 Other aseptically prepared products: Powders Special Requirements: B-lactam antibiotics |
| | 1.1.3 Batch certification |
| 1.5 | Packaging |
| | 1.5.2 Secondary packing |
| 1.6 | Quality control testing |
| | 1.6.1 Microbiological: sterility |
| | 1.6.3 Chemical/Physical |
| | 1.6.4 Biological |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

1.1.1.6 Other aseptically prepared products (Powders): Betalctamic antibiotics;
cephalosporins. ;
1.6.4 Biological: Lal Test;

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A. FLEMING, 2 , 37135 VERONA(VR)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

**PART 1 - MANUFACTURING OPERATIONS OF
INVESTIGATIONAL MEDICINAL PRODUCTS**

| | |
|---------|--|
| 1.1 | Sterile investigational medical products |
| 1.1.1 | Aseptically prepared |
| 1.1.1.6 | Other aseptically prepared products: powder Special Requirements: B-lactam antibiotics |
| 1.6 | Quality control testing |
| 1.6.1 | Microbiological: sterility |
| 1.6.3 | Chemical/Physical |
| 1.6.4 | Biological |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

1.1.1.6 Other aseptically prepared products (powder): Beta-lactamic antibiotics: cephalosporins;

1.6.4 Biological: Lal Test;

Rome, 05/02/2017

Name and signature of the authorised
person of the Competent Authority of
Republic of Italy

Dott. Renato Massimi

GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

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The competent authority of Italy confirms the following:

The manufacturer: GLAXOSMITHKLINE MANUFACTURING S.P.A.

the address: VIA A. FLEMING, 2 - 37136 VERONA (VR)



Apostille

(Convention de La Haye du 5 octobre 1961)

1. Stato: Italia

Il presente atto pubblico

2. è stato firmato da: RIVA ELEONORA

3. operante in qualità di: FUNZIONARIO

4. è munito del sigillo/bollo di: COMUNE DI ROMA

5. in : Roma

6. 01 dicembre 2017

7. da: Prefettura di Roma – Ufficio Territoriale del Governo di Roma

8. col numero: 2947

9. Sigillo/bollo : Prefettura di Roma – Ufficio Territoriale del
Governo di Roma



10. Firma

Funzionario Delegato

Antonella Sergio

Questa
apostille
certifica solo
la qualità del
firmatario e il
sigillo/timbro
che è stato
apposto. Non
certifica il
contenuto
del
documento
per il quale è
stata
rilasciata.